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Remarks

Claims 1-21, 23-28, 30-44, and 68-71 are currently pending.

As a preliminary matter, applicant acknowledges that claims 39-44 and 69-71 have been allowed, and that claims 4-17, 25-28, 30-32, 34, and 36 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. In addition, applicant acknowledges that the response filed February 25, 2003 was sufficient to overcome the previous rejections under 35 U.S.C. § 112, second paragraph, and 35 U.S.C. § 102.

In the present Office Action, claims 1-3, 33, 37, 38, and 68 have been rejected under 35 U.S.C. § 102(b) and/or under 35 U.S.C. § 103(a). Applicant addresses those rejections herein.

Applicant notes that although the Office Action indicates that claim 31 would be allowable upon formal amendments, claim 31 appears to have been mentioned in the rejection under 35 U.S.C. § 102 (see 3<sup>rd</sup> full paragraph on page 3 of the Office Action). Applicant assumes that this is a typographical error, and accordingly, will assume that claim 31 is only being objected to as being dependent on a rejected base claim (as indicated in the 1<sup>st</sup> full paragraph of page 4 of the Office Action).

Rejections Under 35 U.S.C. §§ 102/103

Claims 1-3, 33, 37, 38, and 68 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Munk et al.

(WO 96/01813) or in the alternative under 35 U.S.C. § 103(a) as obvious over Munk et al. Applicant traverses the rejection.

As applicant has indicated previously, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (Emphasis added; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). When a reference is used to anticipate a claim and the reference is silent about the asserted inherent characteristic, extrinsic evidence may be used to fill that gap. "Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference ..." *Continental Can Co. USA Inc. v. Monsanto Co.* 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749-50 (Fed. Cir. 1991) (emphasis added). "Inherency may not be established by probabilities or possibilities." *Scaltech Inc. v. Retec/Tetra L.L.C.* 178 F.3d 1378, 1384, 51 USPQ2d 1055, 1059 (Fed. Cir. 1999) (emphasis added).

Applicant respectfully traverses the rejections under 35 U.S.C. § 102, and submits that Munk et al. does not anticipate the claimed invention because Munk et al. fails to expressly or inherently teach each and every element recited in the claims.

In addition, applicant respectfully submits that the Examiner has not established a *prima facie* case of anticipation. As indicated above, claims can be anticipated if, and only if, a single prior art reference expressly or inherently discloses each and every element recited in the claims. Applicant respectfully requests the Examiner to precisely indicate where

each and every element of the pending claims is expressly or inherently disclosed in Munk et al. Applicant submits that Munk et al. does not specifically expressly or inherently disclose an agent that comprises a therapeutic component and a targeting ligand coupled to the therapeutic component, as recited in the present claims. Absent such express or inherent disclosure, Munk et al. cannot properly be used to anticipate the claimed invention, and the rejection must be withdrawn.

The Office Action states that the claims have added functions which the prior art has not analyzed, and that these added functions are presumed to be inherent in the prior art composition (Office Action, page 3, third full paragraph; emphasis added).

Applicant respectfully submits that a "presumption" of inherency is not a proper basis in rejecting the claims. Either a claimed invention is inherently disclosed by a reference, or it is not inherently disclosed by a reference. To the extent that the Examiner intended to state that the claimed invention is inherently disclosed by Munk et al., applicant reiterates that the missing elements that are not expressly disclosed by a reference, must necessarily be present in the disclosure of the reference to support an inherency rejection. *Continental Can Co. USA Inc. v. Monsanto Co.*, supra.

As discussed above, applicant submits that the Examiner has not established a *prima facie* case of inherency, and applicant respectfully requests the Examiner to specifically indicate where Munk et al. inherently discloses each and every element recited in the claims. Furthermore, the Examiner has already

conceded that the compounds disclosed by Munk et al. do not necessarily disclose the claimed invention by stating that "the prior art and the instant application prepare and use composition which appeared to be identical ..." (Office Action, page 3, last paragraph; emphasis added). As indicated above, inherency cannot be based on probabilities or possibilities, and therefore, Munk et al. does not inherently disclose the claimed invention.

Furthermore, applicant respectfully disagrees with the Examiner's statement that the claims have added functions that are not analyzed by the prior art. The limitations of the binding activity of the targeting component recited in the claims are definitional of the properties of the targeting component, and are not functional characterizations of the claimed agents.

The Office Action further states that "both the prior art and the instant application prepare and use composition [sic] which appeared to be identical for therapy. The prior art therefore suggests that the composition [sic] therein disclosed are effective in such therapy therefore suggesting the instant application under 35 U.S.C. § 103(a)." The Examiner points to *In re Fitzgerald* ( 205 USPQ, page 594, 2<sup>nd</sup> column, 1<sup>st</sup> full paragraph) to support the position that the burden of proof is on the applicant to demonstrate the novelty and unobviousness of the claims.

Applicant respectfully submits that the burden of proof only shifts to the applicant after the Patent Office presents a *prima facie* case of anticipation or obviousness (*In re*

*Rijckaert*, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) citing *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); emphasis ours).

As indicated above, applicant submits the Examiner has not established a *prima facie* case of anticipation/inherency, and applicant submits that the Examiner has not established a *prima facie* case of obviousness. Only after the Examiner has established a *prima facie* case does the burden shift to the applicant. Because the Examiner has not established a *prima facie* case, the burden remains with the Examiner to demonstrate that the claimed invention is anticipated or obvious over Munk et al. For example, applicant submits that Munk et al. does not disclose, teach, or even suggest, and provides no motivation to one of ordinary skill in the art for modifying the compounds disclosed by Munk et al. to obtain the claimed invention. Before the burden shifts to the applicant, applicant submits that the Patent Office bears the burden of specifically showing where Munk et al. discloses an agent including a therapeutic component and a targeting ligand coupled to the therapeutic component, as recited in the present claims. As the Federal Circuit has clearly indicated, "[a]lthough a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be clear and particular." (*In re Dembiscak*, 175 F.3d 994, 999 (CAFC) 1999) emphasis ours). Absent such a clear and particular showing, the burden is not shifted to applicant, and the rejections cannot be maintained and must be withdrawn.

In view of the above, applicant submits that the present claims 1-3, 33, 37, 38, and 68 are not anticipated by, and are

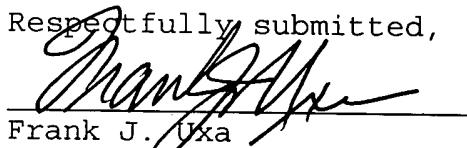
not rendered obvious over, Munk et al. under 35 U.S.C. §§ 102(b) and 103(a).

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present agents and methods for making the agents including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-21, 23-28, 30-44, and 68-71 are allowable. Therefore, applicant requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: JULY 15, 2003

Respectfully submitted,

  
Frank J. Uxa  
Attorney for Applicant  
Registration No. 25,612  
4 Venture, Suite 300  
Irvine, California 92618  
(949) 450-1750  
(949) 450-1764 Facsimile